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West-Ward Pharmaceutical Corp.*

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

**MUTUAL PHARMACEUTICAL COMPANY,
INC., *et al.***

Plaintiffs,

v.

**WATSON PHARMACEUTICALS, INC., *et al.*
Defendants.**

**WEST-WARD PHARMACEUTICAL CORP.
Counterclaimant,**

v.

**MUTUAL PHARMACEUTICAL COMPANY,
INC., *et al.*,
Counterdefendants.**

Civil Action No. 09-5421 (GEB) (TJB)

**DEFENDANT AND
COUNTERCLAIMANT WEST-
WARD PHARMACEUTICAL
CORP'S FIRST AMENDED
COUNTERCLAIMS**

Pursuant to FED. R. CIV. P. 15(a)(2), and with the express written consent of
Plaintiffs Mutual Pharmaceutical Company, Inc., AR Scientific, Inc., and AR Holding
Company, Inc. (collectively, "Plaintiffs"), Defendant and Counterclaimant West-Ward

Pharmaceutical Corp. (“West-Ward”) hereby files its First Amended Counterclaims against Plaintiffs, stating as follows:

1. This Court has supplemental jurisdiction over these counterclaim pursuant to 15 U.S.C. § 1367(a), because the claims asserted herein arise out of the same transactions and occurrences alleged in the Complaint so as to form a part of the same case or controversy. This Court also has original jurisdiction because the counterclaims arise under the Lanham Act, 15 U.S.C. § 1125(a), with original jurisdiction vested by virtue of 15 U.S.C. § 1121 and 28 U.S.C. § 1338.

FACTS

2. The counterclaims arise out of Plaintiffs Mutual Pharmaceutical Company, Inc., AR Scientific Co., Inc., and AR Holding Co., Inc.’s (collectively, “Mutual”) calculated efforts to monopolize the market, distribute a product of questionable integrity in their rush to take advantage of their FDA approval, and charge consumers an outrageously high price for a drug that has been marketed and sold in the United States for more than a century.

3. Colchicine has been produced and sold as a prescription drug for decades without FDA approval. Mutual knows this because Mutual itself sold significant quantities of unapproved colchicine over the past decade, and its unapproved colchicine products remain in the pharmaceutical chain of distribution to this day.

4. To date, the FDA, which has the exclusive authority to interpret and enforce the Food, Drug & Cosmetic Act, has elected not to initiate enforcement action against unapproved colchicine tablets.

5. Contrary to Mutual’s allegations in its Complaint, the FDA has not

determined that the sale of unapproved colchicine tablets is “illegal” or “unsafe.”

6. West-Ward has been the overwhelming leader in nationwide colchicine sales at all relevant times.

7. On information and belief, upon obtaining FDA approval for its colchicine tablets, Mutual began representing to purchasers and potential purchasers of West-Ward’s products that West-Ward’s colchicine tablets are unsafe and that the sale of West-Ward’s tablets is illegal. Fed. R. Civ. P. 11 (b)(3).¹

8. Mutual has also undertaken a surreptitious campaign to monopolize the market for colchicine raw material, offering suppliers lucrative deals to discontinue their sales of colchicine to West-Ward and other distributors of colchicine products in the United States. Fed. R. Civ. P. 11 (b)(3).

9. The FDA has not made any determination that West-Ward’s tablets are unsafe or unlawful and, to the contrary, the FDA continues to acquiesce in the sale of West-Ward’s colchicine tablets.

10. Mutual, which itself distributed unapproved colchicine tablets for years prior to seeking and obtaining FDA approval, and still has unapproved colchicine product in the distribution chain, is well aware that the FDA has not taken any enforcement action against the sale of unapproved colchicine tablets.

11. On information and belief, Mutual has taken these actions, and made these misrepresentations directly to West-Ward’s contractual business partners and prospective purchasers in an intentional effort to monopolize the colchicine market. Fed. R. Civ. P. 11 (b)(3).

¹ All references herein to Fed. R. Civ. P. 11(b)(3) shall constitute the “specific identification” of factual allegations under that rule which, West-Ward believes, will likely have evidentiary support after a reasonable opportunity for further investigation or discovery.

12. Mutual has done so knowing that its own product is not a legitimate substitute for West-Ward's product, because Mutual's product is manufactured in material disregard of industry standard good manufacturing practices and pharmacopaeial requirements, such that Plaintiffs advertised specifications, label claims and expiry date cannot be trusted. Fed. R. Civ. P. 11 (b)(3).

13. For example, West-Ward is informed and believes that Mutual's colchicine raw material is sourced from a Sanmar facility in Krishnagiri District, Tamil Nadu, India, that is not GMP (good manufacturing practices) compliant, has never been inspected by FDA, and was cited for severe violations of GMPs by the French Health Authorities AFSSAPS in a recent inspection.

14. On information and belief, Mutual's actions have disrupted and interfered with West-Ward's existing business relationships and prospective economic advantage and have resulted in diminished sales for West-Ward.

FIRST COUNTERCLAIM
(TORTIOUS INTERFERENCE WITH CONTRACTUAL RELATIONS)

15. West-Ward repeats and realleges paragraphs 1 through 14 as if set forth fully herein.

16. West-Ward, the overwhelming leader in colchicine tablet sales in this country, has valid contractual relationships with various purchasers of prescription drugs, including pharmacies and wholesale purchasers.

17. Mutual acted improperly and without privilege by making false statements and material omissions in connection with the promotion of its colchicine tablets, in comparison to and in competition with West-Ward's product. Fed. R. Civ. P. 11 (b)(3).

18. On information and belief, Mutual falsely represented to pharmacists, data service providers and wholesale purchasers of colchicine tablets that West-Ward's

colchicine tablets are unsafe and are being illegally marketed and sold in the United States. Fed. R. Civ. P. 11 (b)(3).

19. On information and belief, Mutual falsely represented that the integrity of its product could be trusted more than West-Ward's product, knowing the significant quality issues that its product faced, and its potential inability to support its own label claims. Fed. R. Civ. P. 11 (b)(3).

20. On information and belief, in making these false representations regarding West-Ward's colchicine tablets, Mutual omitted that the FDA has not decided to seek any enforcement against West-Ward and that the FDA has not reached any determination regarding West-Ward's ability to sell colchicine tablets. Fed. R. Civ. P. 11 (b)(3).

21. On information and belief, Mutual intended its statements and omissions to induce medical professionals, pharmacists and other purchasers of colchicine tablets not to prescribe, or purchase West-Ward's colchicine tablets and, instead, to prescribe and prescribe or purchase Mutual's tablets. Fed. R. Civ. P. 11 (b)(3).

22. On information and belief, Mutual knew that its misrepresentations would be substantially certain to interfere with West-Ward's existing business relationships. Fed. R. Civ. P. 11 (b)(3).

23. On information and belief, Mutual's actions have induced medical professionals, pharmacists and other purchasers of colchicine tablets not to prescribe, recommend or purchase West-Ward's tablets. Fed. R. Civ. P. 11 (b)(3).

24. By reason of Mutual's acts alleged herein, West-Ward has suffered, and will continue to suffer, damage to its business, reputation and good will and the loss of sales and profits West-Ward would have obtained but for Mutual's acts.

25. In addition to the monetary damages suffered by West-Ward as a direct and proximate result of Mutual's actions, West-Ward has suffered damage to its reputation and the reputation of its colchicine tablets that cannot be adequately compensated by monetary damages. Hence, West-Ward is entitled to permanent

injunctive relief.

26. West-Ward is informed and believes and, based thereon, alleges that the above acts by Mutual were done intentionally, with malice, fraud and/or oppression toward West-Ward, and with the intent of injuring West-Ward in its business or in such conscious disregard of its rights that West-Ward is entitled to an award of exemplary or punitive damages against Mutual in an amount according to proof.

SECOND COUNTERCLAIM
(TORTIOUS INTERFERENCE WITH PROSPECTIVE ECONOMIC ADVANTAGE)

27. West-Ward repeats and realleges paragraphs 1 through 26 of its Counterclaim as if set forth fully herein.

28. West-Ward, the one-time overwhelming leader in colchicine tablet sales in this country, had stable, continuous, and often exclusive business relationships with various purchasers of prescription drugs, including wholesalers, distributors, drug store chains, and pharmacies.

29. West-Ward's colchicine tablets are substantially less expensive and were in higher demand than Mutual's comparable tablets.

30. West-Ward had a reasonable expectation of continuing its business relationships and of obtaining a substantial economic advantage as a result of its long-standing business relationships and reliable, affordable colchicine products.

31. Mutual acted intentionally, maliciously and without justification or excuse by making false statements and material omissions in connection with the promotion of its own colchicine tablets, in comparison to and in competition with West-Ward's colchicine tablets. Fed. R. Civ. P. 11 (b)(3).

32. On information and belief, Mutual falsely represented to pharmacists, drug store chains, data service providers and wholesale purchasers of colchicine tablets that West-Ward's colchicine tablets are unsafe and are being illegally marketed and sold in

the United States. Fed. R. Civ. P. 11 (b)(3).

33. On information and belief, Mutual falsely represented that the integrity of its product could be trusted more than West-Ward's product, knowing the significant quality issues that its product faced, and its potential inability to support its own label claims. Fed. R. Civ. P. 11 (b)(3).

34. On information and belief, in making these false representations regarding West-Ward's colchicine tablets and its own COLCRYS tablets, Mutual omitted that the FDA has not decided to seek any enforcement against West-Ward and that the FDA has not reached any determination regarding West-Ward's ability to sell its colchicine tablets. Fed. R. Civ. P. 11 (b)(3).

35. On information and belief, in making these false representations regarding West-Ward's colchicine tablets, Mutual omitted that West-Ward likely is not required to obtain FDA approval in order to distribute its colchicine tablets. Fed. R. Civ. P. 11 (b)(3).

36. On information and belief, Mutual intended its statements and omissions to induce medical professionals, pharmacists and other purchasers of colchicine tablets not to prescribe, recommend or purchase West-Ward's colchicine tablets and, instead, to prescribe and purchase Mutual's more expensive and less popular colchicine tablets. Fed. R. Civ. P. 11 (b)(3).

37. On information and belief, Mutual knew that its misrepresentations would be substantially certain to interfere with West-Ward's business and cause the loss of prospective gain. Fed. R. Civ. P. 11 (b)(3).

38. On information and belief, Mutual's actions have induced medical professionals, pharmacists and other purchasers of colchicine tablets not to prescribe, recommend or purchase West-Ward's tablets. Fed. R. Civ. P. 11 (b)(3).

39. On information, Mutual's actions have caused purchasers of colchicine tablets to improperly question the safety, legality and efficacy of West-Ward's colchicine tablets. Fed. R. Civ. P. 11 (b)(3).

40. By reason of Mutual's acts alleged herein, West-Ward has suffered, and will continue to suffer, damage to its business, reputation and good will, and the loss of sales and profits West-Ward would have obtained but for Mutual's acts.

41. In addition to the monetary damages suffered by West-Ward as a direct and proximate result of Mutual's actions, West-Ward has suffered damage to its reputation and the reputation of its colchicine tablets that cannot be adequately compensated by monetary damages. Hence, West-Ward is entitled to permanent injunctive relief.

THIRD COUNTERCLAIM
(FALSE ADVERTISING – LANHAM ACT)

42. West-Ward repeats and realleges paragraphs 1 through 41 as if set forth fully herein.

43. Mutual markets its COLCRYS product to drug databases, wholesalers, distributors, drug store chains, pharmacies, and others in interstate commerce as a substantially safer product than West-Ward's colchicine tablets.

44. Mutual intends for potential customers and influential industry organizations to believe that its COLCRYS tablets are superior to and safer than West-Ward's colchicine tablets, despite knowing the significant quality issues that its product faces, and its potential inability to support its own label claims. Fed. R. Civ. P. 11 (b)(3).

45. Mutual is engaged in a marketing campaign designed to give Mutual monopoly status in the colchicine industry. Fed. R. Civ. P. 11 (b)(3).

46. Mutual falsely represents to potential customers, Price Lists and influential industry organizations, in addition to the general public, that West-Ward's colchicine tablets are illegal and that West-Ward is unlawfully distributing its colchicine products, despite the fact that the FDA has not reached any determination regarding West-Ward's ability to sell its colchicine tablets and has taken no enforcement action against West-

Ward. Fed. R. Civ. P. 11 (b)(3).

47. On information and belief, and without limitation, Mutual has represented that Mutual's COLCRYS tablets are the only lawful colchicine tablets on the market, and that West-Ward's continued sale of its unapproved colchicine tablets is illegal. Fed. R. Civ. P. 11 (b)(3).

48. By way of further example, and without limitation, Mutual's CEO, Dr. Richard Roberts, was quoted on December 29, 2009 as stating that, "[t]he companies pushing out illegal products with no regard for safety issues didn't add value for patients and doctors that we've now created. We've revolutionized how colchicine can be used. We don't compare ourselves to illegal products."

49. Mutual's promotional claims about its products are literally and/or impliedly false and misleading. Mutual does not have the necessary factual support showing that its COLCRYS tablets are superior to or safer than to West-Ward's colchicine tablets. Furthermore, Mutual has no factual support for its representations that West-Ward's colchicine tablets are illegal.

50. Mutual's promotional claims violate Section 43(a) of the Lanham Act, which provides in relevant part that any "person who, or in connection with any goods or services . . . uses in commerce any . . . false or misleading description of fact or misleading representation of fact, which . . . in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable to a civil action by any person who believes that he or she is likely to be damaged by such act."

51. Mutual's false, deceptive and misleading advertising has the capacity to deceive customers and is likely to influence customers' purchasing decisions.

52. Mutual's false, deceptive, and misleading advertisements have a material effect on customers' purchasing decisions.

53. By reason of Mutual's conduct, West-Ward has suffered, and will

continue to suffer, damage to its business, reputation, and goodwill. Pursuant to 15 U.S.C. § 1117, West-Ward is entitled to damages for Mutual's Lanham Act violations, an accounting of profits made by Mutual on sales of its COLCRYS tablets, which are wrongfully positioned as the only lawful colchicine tablets on the market, as well as recovery of costs of this action.

54. Mutual's acts are willful, wanton, and calculated to deceive, and are undertaken in bad faith, making this an exceptional case entitling West-Ward to recover additional damages and reasonable attorney fees pursuant to 15 U.S.C. § 1117. Fed. R. Civ. P. 11 (b)(3).

55. Mutual's false and misleading advertising has caused irreparable harm to West-Ward, and unless enjoined by this Court, will continue to irreparably injure West-Ward's goodwill and erode West-Ward's market share. Pursuant to 15 U.S.C. § 1116, West-Ward is entitled to preliminary and permanent injunctive relief to prevent Mutual's continuing acts.

FOURTH COUNTERCLAIM
(UNFAIR COMPETITION – LANHAM ACT)

56. West-Ward repeats and realleges paragraphs 1 through 55 as if set forth fully herein.

57. West-Ward, the one-time overwhelming leader in colchicine tablet sales in this country, had stable, continuous, and often exclusive business relationships with purchasers of prescription drugs, including pharmacies and wholesale purchasers.

58. Mutual markets its COLCRYS tablets as a superior and safer product than West-Ward's colchicine tablets, despite knowing the significant quality issues that its product faced, and its potential inability to support its own label claims. Fed. R. Civ. P. 11 (b)(3).

59. Mutual also markets its COLCRYS products as the only lawful colchicine

tablets on the market, despite the fact that the FDA has taken no enforcement action against other suppliers of colchicine tablets or reached a determination as to the legality of their colchicine tablets. Fed. R. Civ. P. 11 (b)(3).

60. In making the representations referenced above, Mutual has deceived, misled, and confused consumers. Fed. R. Civ. P. 11 (b)(3).

61. Mutual's acts constitute unfair competition in violation of Section 43(a) of the Lanham Act.

62. By reason of Mutual's conduct, West-Ward has suffered, and will continue to suffer, damage to its business, reputation, and goodwill. Pursuant to 15 U.S.C § 1117, West-Ward is entitled to damages for Mutual's Lanham Act violations, an accounting of profits made by Mutual on sales of their products, and recovery of West-Ward's costs of this action.

63. Mutual's acts are willful, wanton, and calculated to deceive, and are undertaken in bad faith, making this an exceptional case entitling West-Ward to recover additional damages and its reasonable attorney fees pursuant to 15 U.S.C § 1117. Fed. R. Civ. P. 11 (b)(3).

64. Mutual's conduct has caused, and unless enjoined by the Court, will continue to cause immediate and irreparable harm to West-Ward for which there is no adequate remedy at law, and for which West-Ward is entitled to injunctive relief.

FIFTH COUNTERCLAIM
(COMMON LAW UNFAIR COMPETITION)

65. West-Ward repeats and realleges paragraphs 1 through 64 as if set forth fully herein.

66. West-Ward, the overwhelming leader in colchicine tablet sales in this country, had stable, continuous, and often exclusive business relationships with various purchasers of prescription drugs, including pharmacies and wholesale purchasers.

67. Mutual has made false and misleading explicit and implicit representations to wholesalers, pharmacists, and others, that its COLCRYS tablets are a superior and safer product than West-Ward's colchicine tablets, despite knowing the significant quality issues that its product faced, and its potential inability to support its own label claims. Fed. R. Civ. P. 11 (b)(3).

68. Mutual has also made false and misleading explicit and implicit representations to wholesalers, pharmacists, and others, that its COLCRYS product are the only lawful colchicine tablets on the market, despite the fact that the FDA has taken no enforcement action against other suppliers of colchicine tablets. Fed. R. Civ. P. 11 (b)(3).

69. Mutual's false and misleading statements about West-Ward's colchicine tablets and its own COLCRYS tablets, and omission of relevant facts, are likely to cause confusion, mistake, or deception about the nature, characteristics, and qualities of the COLCRYS tablets in comparison, connection, or association with West-Ward's colchicine tablets. Fed. R. Civ. P. 11 (b)(3).

70. Mutual's actions are intentional, willful and have been undertaken with the purpose of deceiving consumers. Fed. R. Civ. P. 11 (b)(3).

71. Mutual's conduct has caused, and unless enjoined by the Court, will continue to cause immediate and irreparable harm to West-Ward for which there is no adequate remedy at law, and for which West-Ward is entitled to injunctive relief.

72. West-Ward is entitled to damages for Mutual's unfair competition, an accounting of profits made on sales of Mutual's COLCRYS products and recovery of West-Ward's costs of this action.

WHEREFORE, West-Ward respectfully requests the Court to enter judgment in its favor and to grant the following relief:

1. Enter judgment in favor of West-Ward on each of its counterclaims, and award compensatory as well as punitive damages in West-Ward's favor according to proof,
2. Grant injunctive relief on West-Ward's counterclaims prohibiting Mutual from engaging in the following conduct:
 - (a) making any false or misleading statements or material omissions in connection with the promotion of Mutual's colchicine tablets, in comparison to and in competition with West-Ward's product, including but not limited to:
 - (i) representing to pharmacists, data service providers and wholesale purchasers of colchicine tablets that West-Ward's colchicine tablets are unsafe and are being illegally marketed and sold in the United States; and
 - (ii) representing that the integrity of its product can be trusted more than West-Ward's product, knowing the significant quality issues that its product faces, and its potential inability to support its own label claims; and
 - (b) otherwise engaging in conduct to wrongfully interfere with West-Ward's relationships with its customers, including pharmacies and wholesale purchasers.
3. Award West-Ward its costs, attorneys' fees and expenses incurred herein; and
4. Grant such other relief as the Court may deem just and proper.

Respectfully submitted,

/s/Michael Dore

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